

DOCKET NO.: PHOE-0188

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Mike A. Clark

Application No.: 10/757,843

Filing Date: January 15, 2004

For: MODIFIED ARGININE DEIMINASE

Confirmation No.:

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT: Aug. 16, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.


TYPED NAME: Patrick J. Farley
REGISTRATION NO.: 42,524

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

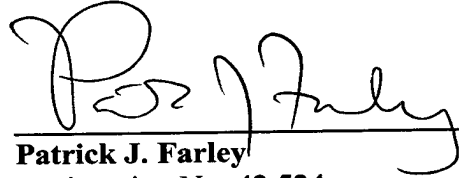
EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☒ Copies of references **1 thru 46 and 52 thru 71** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/723,546** filed **November 28, 2000**.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Enclosed is a copy of EPO Partial European Search Report dated **July 19, 2004**, which indicates the references to be relevant.

Date: *Aug. 16, 2004*


Patrick J. Farley
Registration No. **42,524**

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. PHOE-0188	Application No. 10/757,843
		Applicant Mike A. Clark	
		Filing Date January 15, 2004	Group Not Yet Assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	1	Abuchowski, A. et al., "Effect of Covalent Attachment of Polyethylene Glycol on Immunogenicity and Circulating Life of Bovine Liver Catalase", <i>J. Biol. Chem.</i> , 1977 , 252(11), 3582-3586	
	2	Abuchowski, A., et al., "Treatment of L5178Y Tumor-Bearing BDF Mice with a Nonimmunogenic-Asparaginase", <i>Cancer Terat. Rep.</i> , 1979 , 63(6), 1127-1132	
	3	Gill, P. et al., "Inhibition of Cell Division in L5178Y Cells by Arginine-Degrading Mycoplasmas: The Frole of Arginine Deiminase", <i>Can. J. Microbiol.</i> , 1970 , 16, 415-419	
	4	Habeeb, A.F.S.A., "Determination of Free Amino Groups in Proteins by Trinitrobenzenesulfonic Acid", <i>Analyt. Biochem.</i> , 1966 , 14, 328-336	
	5	Hershfield, M.S. et al., "Treatment of Adenosine Deaminase", <i>New Engl. J. Medicine</i> , 1987 , 316(10), 589-596	
	6	Jaffe, N. et al., "Favorable Remission Induction Rate with Twice Weekly Doses of l-Asparaginase", <i>Cancer Res.</i> , 1973 , 33(1), 1-4	
	7	Jones, J.B., "The Effect of Arginine Deiminase on Murine Leukemic Lymphoblasts", <i>Ph.D. Dissertation, The University of Oklahoma</i> , 1981 , 1-165	
	8	Kamisaki, et al., "Increased Antitumor Activity of Escherichia Coli l-Asparaginase by Modification with Monomethoxypolyethylene Glycol", <i>Gann</i> , 1982 , 73-470-474	
	9	Kamisaki, et al., "Reduction in Immunogenicity and Clearance Frate of Escherichia Coli l-Asparaginase by Modification with Monomethoxypolyethylene Glycol", <i>J. Pharmacol. Exp. Ther.</i> , 1981 , 216(2), 410-414	
	10	Kidd, J.G. "Aspariginase and Cancer-Yesterday and Today", <i>Cancer Res.</i> , 1970 , 33, 1-14	
EXAMINER		DATE CONSIDERED	

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. PHOE-0188	Application No. 10/757,843
	Applicant Mike A. Clark	
	Filing Date January 15, 2004	Group Not Yet Assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	11	Kondo, K. et al., "Cloning and Sequence Analysis of the Arginine Deiminase Gene from Mycoplasma Arginini", <i>Mol. Gen. Genet.</i> , 1990 , 221, 81-86
	12	Misawa, S. et al., "High-Level Expression of Mycoplasma Arginine Deiminase in Escherichia Coli and Its Efficient Renaturation as an Anti-Tumor Enzyme", <i>J. Biotechnology</i> , 1994 , 36, 145-155
	13	Miyazaki, K. et al., "Potent Growth Inhibition of Human Tumor Cells in Culture by Arginine Deiminase Purified from a Culture Medium of a Mycoplasma-Infected Cell Line", <i>Cancer Res.</i> , 1990 , 50, 4522-4527
	14	Monfardini, C. et al., "A Branched Monomethoxypoly(Ethylene Glycol) for Protein Modification", <i>Bioconj. Chem.</i> , 1995 , 6, 62-69
	15	Naio, M. et al., "Alteration of the Substrate Specificity of Aspergillus Oryzae β -Galactosidase by Modification with Polyethylene Glycol", <i>J. Appl. Biochem.</i> , 1984 , 6, 91-102
	16	Oginsky, "[92] Isolation and Determination of Arginine and Citrulline", <i>Meth. Enzymol.</i> , 1957 , 3, 639-642
	17	Ohno, T. et al., "Cloning and Nucleotide Sequence of the Gene Encoding Arginine Deiminase of Mycoplasma Arginini", <i>Infect. Immun.</i> , 1990 , 58, 3788-3795
	18	Park, Y.K. et al., "Pharmacology of Escherichia Coli-L-Asparaginase Polyethylene Glycol Adduct", <i>Anticancer Res.</i> , 1981 , 1, 373-376
	19	Pyatak, P.S. et al., "Preparation of a Polyethylene Glycol: Superoxide Dismutase Adduct and an Examination of its Blood Circulating Life and Anti-Inflammatory Activity", <i>Res. Commun. Chem. Path. Pharmacol.</i> , 1980 , 29(1), 113-127
	20	Sayers, J.R. et al., "Rapid High-Efficiency Site Directed Mutagenesis by the Phosphorothioate Approach", <i>Biotechniques</i> , 1992 , 13(4), 592-596
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. PHOE-0188	Application No. 10/757,843
	Applicant Mike A. Clark	
	Filing Date January 15, 2004	Group Not Yet Assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	21	Stocks, S.J. et al., "A Fluorometric Assay of the Degree of Modification of Protein Primary Amines with Polyethylene Glycol", <i>Analyt. Biochem.</i> , 1986 , 154, 232-234
	22	Su, T. et al., "Cloning of cDNA for Argininosuccinate Synthetase mRNA and Study of Enzyme Overproduction in a Human Cell Line", <i>J. Biol. Chem.</i> , 1981 , 256(22), 11826-11831
	23	Sugimura, K. et al., "High Sensitivity of Human Melanoma Cell Lines to the Growth Inhibitory Activity of Mycoplasma Arginine Deiminase in Vitro", <i>Melanoma Res.</i> , 1992 , 2, 191-196
	24	Sugimura, K. et al., "Identification and Purification of Arginine Deiminase that Originated from Mycoplasma Arginini", <i>Infect Immun.</i> , 1990 , 58*8, 2510-2515
	25	Takaku, H. et al., "Anti-tumor Activity of Arginine Deiminase from Mycoplasma Arginini and its Growth-Inhibitory Mechanism", <i>Int. J. Cancer</i> , 1995 , 86, 840-846
	26	Takaku, H. et al., "Chemical Modification by Polyethylene Glycol of the Anti-Tumor Enzyme Arginine Deiminase from Mycoplasma Arginini", <i>Jpn. J. Cancer Res.</i> , 1993 , 84, 1195-1200
	27	Takaku, H. et al., "In Vivo Anti-Tumor Activity of Arginine Deiminase Purified From Mycoplasma Arginini", <i>Int. J. Cancer</i> , 1992 , 51, 244-249
	28	Teske, E. et al., "Polyethylene Glycol-L-Asparaginase Versus Native L-Asparaginase in Canine Non-Hodgkin's Lymphoma", <i>Eur. J. Cancer</i> , 1990 , 26(8), 891-895
	29	Zalipsky, et al., "Use of Functionalized Poly(Ethylene Glycol)s for Modification of Polypeptides", <i>Polyethylene Glycol Chem., Biotechnical and Biomedical Applns.</i> , 1992 , 21, 347-370
	30	Misawa, S. et al., "High-Level Expression of <i>Mycoplasma</i> Arginine Deiminase in <i>Escherichia coli</i> and its Efficient Renaturation as an Anti-Tumor Enzyme", <i>J. Biotechnology</i> , 1994 , 36, 145-155
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. PHOE-0188	Application No. 10/757,843
	Applicant Mike A. Clark	
	Filing Date January 15, 2004	Group Not Yet Assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	31	van Wagendonk, et al., "Nitrogen metabolism in protozoa", <i>Comparative Biochemistry of Nitrogen Metabolism (J.W. Campbell ed.)</i> , 1970, 1-56
	32	Chang, et al. "Arginase modulates nitric oxide production in activated macrophages", <i>Am. J. Physiol: Heart and Circul. Physiol.</i> , 1998, 274, H342-H348
	33	McDonald, et al., "A Caveolar complex between the cationic amino acid transporter 1 and endothelial nitric-oxide synthase may explain the "Arginine paradox", <i>J. Biol. Chem.</i> , 1997, 272, 31213-31216
	34	Deckers, P.J, et al. "The effect of tumor size on concomitant tumor immunity", <i>Cancer Res.</i> , 1973, 33(1), 33-39
	35	Fenske, J.D., et al., "Role of arginine deiminase in growth of <i>Mycoplasma hominus</i> ", <i>J. Bacteriol.</i> , 1976, 126, 501-510
	36	Lang, K. et al., "Catalysis of protein folding by prolyl isomerase", <i>Nature</i> , 1987, 329, 268-270
	37	Craig, S. et al., "Single amino acid mutations block a late step in the folding of B-Lactamase from <i>Staphylococcus aureus</i> ", <i>J. Mol. Biol.</i> , 1985, 185, 681-687
	38	Joppich, et al., "Peptides flanked by two polymer chains, 1-synthesis of Glycyl-L-tryptophylglycine substituted by poly(ethylene oxide) at both the carboxy and the amino end groups", <i>Macromol. Chem.</i> , 1979, 180, 1381-1385
	39	Harasawa, R. et al., "Nucleotide Sequence of the Arginine Deiminase Gene of <i>Mycoplasma hominis</i> ," <i>Microbiol. Immunol.</i> , 1992, 36(6), 661-665
	40	Takaku, H. et al., "Anti-tumor Activity of Arginine Deiminase from <i>Mycoplasma arginini</i> and Its Growth-inhibitory Mechanism," <i>Jpn. J. Cancer Res.</i> , September 1995, 86(9), 840-846
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. PHOE-0188	Application No. 10/757,843
	Applicant Mike A. Clark	
	Filing Date January 15, 2004	Group Not Yet Assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	41	Fraser, C. et al., "Borrelia burgdorferi (section 69 of 70) of the complete genome", 12/16/1997 , Database Accession no. AE001183, XP 002211866
	42	Knodler, Leigh A. et al., "Cloning and Expression of a Prokaryotic Enzyme, Arginine Deiminase., from a Primitive Eukaryote <i>Giardia intestinalis</i> ", <i>Journal of Biological Chemistry</i> , 02/20/1998 , 273(8), 4470-4477, XP-002211868
	43	Takaku, et al., <i>Jpn J. Cancer Res.</i> , 1993 , 84, 1195-200
	44	Poyart, et al., <i>International Journal of Systematic and Evolutionary Microbiology</i> , 2002 , 52, 1247-1255
	45	Tettelin, et al., <i>Science</i> , 2001 , 293, 498-506
	46	Degnan, et al., <i>Infection and Immunity</i> , 1998 , 66(7), 3050-3058
	47	Clark, R., et al., "Long-Acting Growth Hormones Produced by Conjugation with Polyethylene Glycol", <i>journal of Biological Chemistry</i> , 1996 , 271, 21969-21977, XP-002216386
	48	Gaertner, H.F. et al., "Site-Specific Attachment of Functionalized Poly(Ethylene Glycol) to the Amino Terminus of Proteins", <i>Bioconjugate Chem.</i> , 1996 , 7, 38-44, XP-000791225
	49	Kita, Y. et al., "Characterization of a Polyethylene Glycol Conjugate of Recombinant Human Interferon- γ ", <i>Drug Design and Delivery</i> , 1990 , 6, 157-167
	50	Rigneault, H. et al., "Extraction of Light from Sources Located Inside Waveguide Grating Structures", <i>Optice Letters</i> , 1999 , 24(3), 148-150, XP-000803121
	51	Molnar, S. et al., "Pharmacology of a Peg-Conjugated Arginine Deiminase", <i>Faseb Journal</i> , 1993 , 7, pg A391, XP009002632
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office				Docket No. PHOE-0188		Application No. 10/757,843	
				Applicant Mike A. Clark			
				Filing Date January 15, 2004		Group Not Yet Assigned	
U. S. PATENT DOCUMENTS							
Examiner Initial		Document No.	Date	Name	Class	Subclass	
	52	4,179,337	12/18/79	Davis, et al.	435	181	
	53	4,609,546	09/02/86	Hiratani	424	83	
	54	5,447,722	09/05/95	Lang, et al.	424	280.1	
	55	5,468,478	11/21/95	Saifer, et al.	424	78.27	
	56	5,474,928	12/12/95	Takaku, et al.	435	228	
	57	5,372,942	12/94	McGarrity, et al.	435	227	
	58	5,804,183	08/98	Filpula, et al.	424	94.6	
	59	5,916,793	06/02/99	Filpula, et al.	435	195	
FOREIGN PATENT DOCUMENTS							
Examiner Initial		Document No.	Date	Country	Translation		
					YES	NO	
	60	WO 94/05332	03/17/94	PCT			
	61	WO 96/34015	10/31/96	PCT			
	62	JP 4 121 187	04/22/92	Japan			
	63	EP 0 372 752 A2	06/13/90	EPO			
	64	JP 53490	02/22/90	Japan			
EXAMINER				DATE CONSIDERED			

Form PTO-1449 Modified

List of Patent and Publications
Cited by Applicant
(Use several sheets if necessary)

U.S. Department of Commerce
Patent and Trademark Office

Docket No.
PHOE-0188

Application No.
10/757,843

Applicant
Mike A. Clark

Filing Date
January 15, 2004

Group
Not Yet Assigned

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	65	6,132,713	10/17/00	Fiipula, et al.	424	94.3

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	66	EP 0 230 777 A1	08/87	EPO		
	67	EP 0 414 007 A2	02/27/91	EPO		
	68	EP 0 897 011 A2	02/17/99	EPO		
	69	WO 98/33519	08/06/98	PCT		
	70	WO 98/51784	11/19/98	PCT		
	71	JP 3 209 338	09/17/01	Japan		
	72	EP 0 442 724 A2	08/21/91	EPO		

EXAMINER**DATE CONSIDERED**